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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,344	09/02/2005	David J. Kyle	026086.033.210 US	1584
24239 7590 11/27/2009 MOORE & VAN ALLEN PLLC P.O. BOX 13706 Research Triangle Park, NC 27709				
EXAMINER				
BERTOGGIO, VALARIE E				
ART UNIT		PAPER NUMBER		
1632				
MAIL DATE		DELIVERY MODE		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/532,344

**Applicant(s)**

KYLE ET AL.

**Examiner**

Valarie Bertoglio

**Art Unit**

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4-15, 18-33 and 35-45 is/are pending in the application.
- 4a) Of the above claim(s) 4-14, 18-33, 38-42, 44 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 15, 35 and 43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

#### **DETAILED ACTION**

Applicant's reply filed on 08/31/2009 has been entered.

Claims 1-3,16-17,34,36-37 are cancelled. Claims 4-14,18-33, 38-42,44 and 45 are withdrawn. Claims 15 and 35 are amended. Claims 15,35 and 47 are under consideration.

This application contains claims 4-14,18-33, 38-42,44 and 45 drawn to an invention nonelected with traverse in the reply filed on 04/19/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

#### ***Claim Rejections - 35 USC § 112-1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 16-17 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is rendered moot by the cancellation of the claims.

Claims 15, 35 and 43 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing shrimp exhibiting a DHA:EPA ratio of greater than 1 comprising feeding shrimp a standard shrimp feed supplemented with Schizochytrium sp., does not reasonably provide enablement for the claimed method or resulting shrimp using any other species of microalga. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to shrimp or methods of raising them aquaculturally wherein said shrimp comprise a DHA:EPA ratio greater than 1.0.

The specification teaches feeding shrimp either *Cryptocodinium* sp or *Schizochytrium* sp of algae (page 13, paragraph [048]. The specification shows a modest increase in percent DHA composition in shrimp fed the alga in comparison to those fed a fish oil supplement. In fact, this increase over the control diet appeared in only 1 out of the 2 samples measured (see Table 2 at page 19). However, the Kyle declaration filed 01/25/2009 presents additional data supporting that *Schizochytrium* sp. used as a feed supplement did result in a DHA:EPA ratio of greater than 1.

The art at the time of filing had revealed that some algal species were a food source that can lead to increases in the DHA and EPA composition of shrimps [see for example, Thinh *et al*, **Aquaculture**, 1999, 170:161-173]. However, not all algae lead to such a benefit and those that do enhance DHA content of shrimp, do so to varying degrees dependent upon the DHA content of the algae. Furthermore, even shrimp with higher DHA levels as well as those with control diets failed to have a DHA/EPA content even remotely close to 1.0 as required by the claims. This is also supported by US 6,451,567, which tested a range of different algal species and found that the fatty acid production produced by them was diverse (column 22, lines 54-57). Furthermore, as Applicant pointed out in the remarks dated 01/25/2009, the use of a thraustochytrid-based supplement in '567 did not result in a DHA:EPA > 1.

Thus, the state of the art holds that it is unpredictable whether any particular algae will cause an increase in DHA in shrimp fed the algae and the degree of the increase is also variable. The claims require a DHA/EPA ratio of at least 1.0. Based on the state of the art, only certain feeding conditions would meet these limitations and no feeding conditions have been made of record that lead to a DHA/EPA of at least 1.0 other than *Schizochytrium* sp. The specification teaches feeding *Cryptocodinium* sp. However, the specification does not teach whether this species of algae results in a DHA/EPA ratio to at least 1.0. The specification only teaches a modest increase in DHA in 1 out of 2 samples in terms of some percentage relative an unknown standard. It would require undue experimentation to determine how to make the

shrimp as claimed comprising a DHA/EPA ratio of at least 1 using any species other than Schizochytrium sp.

Applicant has amended claims 15, 35 and 43 to read that the shrimp are fed microalgae or microalgal extracts wherein the microalgae is selected from a number of Schizochytrium species. This limitation is not sufficient to overcome the instant rejection as it encompasses use of microalgal extracts other than Schizochytrium.

Claims 15,35 and 43 encompass use of a novel cell algal species deposited as ATCC 28209. Since the algae is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the cell line is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the algae. 37 CFR 1.802. The specification does not disclose a repeatable process to obtain the algae and it is not apparent if the algae is readily available to the public. Thus, a deposit is required for enablement purpose. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific cell line has been deposited under the Budapest Treaty and that the cell line will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. 37 CFR 1.808

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.808, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a viability statement in accordance with the provisions of 37 CFR 1,807; and
- (e) the deposit will be replaced if it should ever become inviable.

As required under 37 CFR 1.809(d), the specification shall contain: (1) the accession number for the deposit; (2) the date of deposit; (3) a description of the deposited biological material sufficient to identify it and to permit its examination; and (4) the name and address of the depository.

*. Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 35 remains rejected under 35 U.S.C. 102(a) and (c) as being anticipated by US 6,451,567 (patent date 09/17/2002, filed 1999).

Applicant argues that '567 did not teach such a shrimp with a DHA:EPA of greater than 1. However, to the extent that the claimed methods encompass the methods used by '567 and the methods of '567 are aimed at increasing DHA levels in shrimp, the rejection is maintained. The methodology claimed is broad and does not indicate a difference that would result in shrimp that differ in structure or content of that taught in '567. '567 taught feeding multiple algal species, including Schizochytrium. '567 taught that such microflora have feed advantages due to its high Omega-3 (DHA) content (see column 2).

Applicant argues that Example 12 of '567 discloses an algal based feed supplement resulting in fatty acid content as disclosed in Figures 7 and 8, which show DHA levels lower than EPA (i.e. a ratio less than 1). Example 12 of '567 shows feeding *Thaustochytrium* based feed. Thus, the DHA:EPA being less than 1 is irrelevant as the claimed feed differs from that of '567. '567 does teach *Schizochytrium* species of feed which would inherently yield a ratio of greater than 1, given the Kyle Declaration of record. Additionally, Figure 6 of '567 shows the effectiveness of various *Schizochytrium* and *Thaustochytrium* species and total fatty acid yield varied greatly between *Schizochytrium* and *Thaustochytrium* strains. Thus, a DHA:EPA<1 result from feed comprising *Thaustochytrium* fails to correlate to feeding *Schizochytrium*. The claims are not limited to a particular *Schizochytrium* species and to the extent that Applicant argues the claimed *Schizochytrium* species will result in a ratio >1, the *Schizochytrium* species of the art would inherently produce the same result.

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Middelitch (1980, IDS).

Middelitch taught *Penaeus* shrimp with a higher DHA content than EPA, which would be a ratio greater than 1 (see Table IV).

Claim 15 has been amended to read as a product by process type claim. While Middelitch may not have made the product using the process claimed, the process by which the product is obtained carried little patentable weight. This is because the final product is not distinguished by any particular features or

characteristics resulting from the process by which it is made. As such, the limitations of the claimed shrimp are met by the prior art. Patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claims, *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985).

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.



Claim 43 remains rejected under 35 U.S.C. 102(a) and (e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 6,451,567 (patent date 09/17/2002, filed 1999).

Applicant has amended the claim to require the shrimp used in the method be a product of a process argued to not be taught by the prior art. Applicant states that because claim 43 recites the same limiattin as claim 35, claim 43 is not anticipated by '567. In response, these arguments are addressed above regarding claim 35. Furthermore, limiting the use of a shrimp wherein the shrimp was obtained using a particular method has little patentable weight as set forth above for claim 15. The methodology claimed does not indicate a difference that would result in shrimp that differ in structure or content of that taught in '567. '567 taught feeding multiple algal species, including Schizochytrium. '567 taught that such microflora have feed advantages due to its high Omega-3 (DHA) content (see column 2). The claims are not limited to a particular Schizochytrium species and to the extent that Applicant argues the claimed Schizochytrium species will result in a ratio >1, the Schizochytrium species of the art would inherently produce the same result.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are *produced by identical means or substantially identical processes*, a prima facie case of either anticipation or obviousness has been established. In re Best 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best 562 F.2d sat 1255, 195 USPQ 433. See M.P.E.P 2112.01.

See *Integra Life Sciences I Ltd. v. Merck KGaA*, 50 USPQ2d 1846 (DC SCalf, 1999) which teaches that a reference teaching a process may anticipate claims drawn to a method comprising the same process

steps, despite the recitation of a different intended use in the preamble or the later discovery of a particular property of one of the starting materials or end products.

See also *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993), which teaches that a reference teaching a claimed process, wherein one of the claimed properties of a product used in the prior art process is inherent but undisclosed by the reference, may be properly applied as art against the claimed process.

Claims 15,35 and 43 remain rejected under 35 U.S.C. 102(b) and (c) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 99/06585 (published 02/11/1999).

'460 taught feeding microalga to shrimp to increase DHA content. Specifically, *Cryptothecodinium cohnii*, which is the alga used in the instant specification, was dried and DHA phospholipids are collected by centrifugation. The DHA was then blended with the alga *chlorella* and used as a feed. '460 does not teach a shrimp fed the feed would yield a DHA:EPA>1. However, the methods taught by '460 meet the limitations of the method claims and are substantially the same as those taught by the specification to result in the claimed ration in the product. '460 discusses that *Schizochytrium* species that are high in DHA can also be used, which meets the newly recited limitations of the claims.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical means or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that the prior art products

do not necessarily possess the characteristics of the claimed product. In re Best 562 F.2d at 1255, 195 USPQ 433. See M.P.E.P 2112.01.

See *Integra Life Sciences I Ltd. v. Merck KGaA*, 50 USPQ2d 1846 (DC SCalf, 1999) which teaches that a reference teaching a process may anticipate claims drawn to a method comprising the same process steps, despite the recitation of a different intended use in the preamble or the later discovery of a particular property of one of the starting materials or end products.

See also *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993), which teaches that a reference teaching a claimed process, wherein one of the claimed properties of a product used in the prior art process is inherent but undisclosed by the reference, may be properly applied as art against the claimed process.

Applicant argues that '460 cannot anticipate or make obvious the claims as '567 (above) taught feeding of Schizochytrium (ATCC20888) did not result in the requirement of  $>1$ . Thus, '567 is evidence that '420 could not have met the limitation of a ratio  $>1$ . The claims are not limited to a particular Schizochytrium species and to the extent that Applicant argues the claimed Schizochytrium species will result in a ratio  $>1$ , the Schizochytrium species of the art would inherently produce the same result.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Valarie Bertoglio/

Primary Examiner, Art Unit 1632